

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION**

HARDY,
Plaintiff,
v.

ZIMMER et al.,
Defendants.

§
§
§
§
§
§
§
§

Civil Action No. 2:16-cv-242-JRG

MEMORANDUM OPINION AND ORDER

Before the Court are the motions for summary judgment filed by Defendants Zimmer Inc. and Zimmer Biomet Holdings, Inc. f/k/a Zimmer Holdings, Inc. (“Defendants” or “Zimmer”) (Dkt. No. 178) (“Defendants’ Motion”) and Plaintiff Martha Hardy (Dkt. No. 180) (“Plaintiff’s Motion”). Having considered the Motions, the Court is of the opinion that Defendants’ Motion (Dkt. No. 178) should be **GRANTED-IN-PART** and **DENIED-IN-PART** and that Plaintiff’s Motion (Dkt. No. 180) should be **GRANTED-IN-PART** and **DENIED-IN-PART**.

I. Defendants’ Motion for Summary Judgment

a. Medical Causation

Defendants argue that all of Plaintiff’s claims fail as a matter of law due to lack of expert testimony regarding medical causation. As stated and explained in the Court’s ruling at the pre-trial conference on April 12, 2017, the Court finds that Plaintiff’s expert reports, specifically the report of Dr. Edward Adler, provide sufficient evidence regarding medical causation to present a factual dispute as to this issue. As such, Part I of Defendants’ Motion is **DENIED**.

b. Design Defect

Defendants argue that Counts 1 and 2 of Plaintiff's Complaint should be dismissed. Count One of Plaintiff's Complaint includes manufacturing and design defect claims based on strict liability. (Dkt. No. 168 at 15–22.) Count Two includes negligence claims based on negligent design, negligent manufacture, and negligent sale. (Dkt. No. 168 at 22–25.) Part II of Defendants' Motion addresses only the claims related to the alleged design defect.

Defendants argue that Plaintiff cannot prove that the device was unreasonably dangerous as designed, that a safer alternative design existed, or that the design defect was a producing cause of her injury. Plaintiff, however, has presented evidence to demonstrate that a genuine issue of material fact exists as to each of these arguments. Plaintiff argues that the safer alternative design in this case is the original design of the Trilogy shell—namely, the design that included a porosity of 45%. In sum, Plaintiff has presented evidence that could lead a reasonable juror to believe that Defendants chose to implement a design specification that had a lower level of porosity (30%) than was previously represented to the FDA. (*See* Dkt. No. 211-1 at 5; Dkt. No. 211-3 at 2.) Plaintiff has also presented evidence that a device with a higher level of porosity was feasible at the time her device was manufactured. (*See* Dkt. No. 211-2 at 8–9; Dkt. No. 211-5.) Finally based on the medical causation opinions provided by Plaintiff's experts, there is sufficient evidence to create a factual dispute regarding whether this alleged design defect was a producing cause of Plaintiff's injuries. Thus, Part II of Defendants' Motion is **DENIED**.

c. Failure to Warn Claims

Defendants argue that Plaintiff's failure to warn claims, which are based on common law negligence, the DTPA, and alleged negligent misrepresentation, fail due to application of the

learned intermediary doctrine. Specifically, Defendants argue that to recover for failure to warn when the learned intermediary doctrine applies, a plaintiff must show that the warning was defective and that the failure to warn was a producing cause of the plaintiff's injuries. Defendants argue that Plaintiff's failure to warn claims fail as to both prongs. (Dkt. No. 178 at 17–18.)

Plaintiff has presented sufficient evidence to show that a genuine issue of material fact as to each of these arguments. Specifically, Plaintiff has pointed to testimony by Dr. Phillips that indicates that porosity is always a concern from his perspective. (*See* Dkt. No. 211-17 at 17.) From this, a reasonable fact-finder could conclude that Zimmer had a duty to disclose the fact that it did not have any processes in place for ensuring the expected percentage of porosity in its devices. Although Defendants also point to testimony from Dr. Phillips, whether such testimony conflicts and whether it is dispositive of this claim is a factual issue. As such, Part III of Defendants' Motion is **DENIED**.

d. Negligent Misrepresentation

Defendants argue that Plaintiff cannot establish that Defendants provided any false information in its package insert and that Plaintiff has no evidence that she or her doctor relied on any representations from Defendants. (Dkt. No. 178 at 22.) A claim for negligent misrepresentation, however, may be based on a failure to disclose information when there is a duty to disclose such information. *Brown & Brown v. Omni Metals, Inc.*, 317 S.W.3d 361 (Tex. App.—Houston [1st Dist.] 2010, pet. denied). Thus, regardless of whether Defendants provided “false” information, Plaintiff has produced evidence that could indicate that Zimmer had a duty to disclose its failure to validate the devices produced at its facility. (*See* Dkt. No. 211-8 at 2.) Moreover, as noted above, Plaintiff has produced at least some evidence that Dr. Phillips considers

porosity important and thus that he may have been concerned regarding a lack of porosity validation. (*See* Dkt. No. 211-17 at 17.) As such, because Plaintiff has presented evidence that indicates the presence of a factual dispute as to these issues, Part IV of Defendants' Motion is **DENIED**.

e. Negligent Marketing

Defendants argue that Plaintiff's negligent marketing claim fails as a matter of law because Plaintiff has not presented competent expert testimony regarding breach of a duty. (Dkt. No. 178 at 23.) For a plaintiff to prevail on a negligent marketing claim, as opposed to a strict liability marketing defect claim, a plaintiff must establish four elements: "1) a duty by [a defendant] to act according to an applicable standard of care; 2) a breach of the applicable standard of care; 3) an injury; and 4) a causal connection between the breach of care and the injury." *Ethicon Endo-Surgery, Inc. v. Gillies*, 343 S.W.3d 205, 211 (Tex. App.—Dallas 2011). After summarizing Texas law regarding whether expert testimony is required in a negligent marketing case, the court in *Ethicon Endo-Surgery* held: "Because we conclude the standard of care in marketing a specialized medical device requiring specialized technique for use is not within the experience of laymen, we must also conclude expert testimony was required to prove negligent marketing of such a device as in this case." *Id.* at 212. Accordingly, the court held that a plaintiff must offer expert testimony that a defendant failed to exercise ordinary care in the marketing of a medical device. *See id.*

In her Response, Plaintiff fails to clearly identify any expert testimony that would be relevant to breach of a duty. If such testimony is included somewhere within the general statement of facts and exhibits included at the beginning of Plaintiff's Motion, it is not apparent to the Court

where such evidence can be found. Moreover, Plaintiff has failed to specifically reference any such evidence in the section of her response that addresses negligence. “Judges are not like pigs, hunting for truffles buried in briefs,” and the Court is unable to locate expert testimony in the record to support Plaintiff’s negligent marketing claim. *de la O v. Hous. Auth. of City of El Paso, Tex.*, 417 F.3d 495, 501 (5th Cir. 2005) (quoting *United States v. Dunkel*, 927 F.2d 955, 956 (7th Cir.1991)). As such, Part V of Defendants’ Motion is **GRANTED**.

f. Negligent failure to recall

In light of Plaintiff’s concession in its Response, indicating that Plaintiff has not pleaded a claim for failure to recall, Part VI of Defendants’ Motion is **GRANTED**. (Dkt. No. 211 at 26.)

g. Affirmative Fraud and Fraud by Nondisclosure

As to Plaintiff’s claim of affirmative fraud, Defendants argue that Plaintiff has no evidence that (1) Zimmer made misrepresentations to Plaintiff or her doctor; or (2) Plaintiff or her doctor relied on such misrepresentations. (Dkt. No. 178 at 24–25.)

Regarding Plaintiff’s fraud by nondisclosure claim, Defendants argue that Plaintiff’s claim fails based on lack of a duty to disclose any of the allegedly omitted information and based on federal preemption of Plaintiff’s state law claim. (Dkt. No. 178 at 25.) Specifically, Zimmer argues that it did not have a duty to disclose anything about its compliance with FDA regulations because no federal or state regulation requires Zimmer to disclose that the device was allegedly “adulterated.” (Dkt. No. 178 at 25.) Although Zimmer cites two cases to support its argument, each of those cases differ significantly from the case at bar because the devices in those two cases had been through the rigorous PMA process, rather than the 510(k) process used to gain approval of the device at issue in this case. *See Bass v. Stryker Corp.*, 669 F.3d 501, 515 (5th Cir. 2012); *Purcel*

v. Advanced Bionics Corp., No. 3:07-CV-1777-M, 2010 WL 2679988, at *6 (N.D. Tex. June 30, 2010).

Defendants further argue that although an affirmative duty can arise by operation of law, such a duty has not arisen in this case. (Dkt. No. 178 at 25–26.) Under Texas law, a duty to disclose may arise “(1) when the parties have a confidential or fiduciary relationship, (2) when one party voluntarily discloses information, which gives rise to the duty to disclose the whole truth, (3) when one party makes a representation, which gives rise to the duty to disclose new information that the party is aware makes the earlier representation misleading or untrue, or (4) when one party makes a partial disclosure and conveys a false impression, which gives rise to the duty to speak.” *Solutioneers Consulting, Ltd. v. Gulf Greyhound Partners, Ltd.*, 237 S.W.3d 379, 385 (Tex. App.—Houston [14th Dist] 2007, no pet.). Based on the evidence presented by Plaintiff, the Court is persuaded that there are unresolved fact issues regarding whether circumstances existed under which a duty to disclose arose in this case, particularly with respect to the alleged lack of validation processes. (See Dkt. No. 211-8 at 2.)

As to Defendants’ second argument—that Plaintiff’s fraud by nondisclosure claim is impliedly preempted by federal law under *Buckman Co. vs. Plaintiffs’ Legal Committee*, 531 U.S. 341 (2001)—this argument also fails at this stage of the case. Plaintiff notes that unlike the claims in *Buckman*, her claims are based on Zimmer’s actions and omissions directed at her—not Zimmer’s actions and omissions directed toward the FDA. (Dkt. No. 211 at 28.)

Although the pleadings from both parties in this case are less than clear as to their respective factual bases, the Court is persuaded that Plaintiff’s fraud-based claims may contain at least one factual theory that would not be preempted under *Buckman*. As such, the Court finds it

appropriate to **DENY** summary judgment as to Defendant's preemption argument at this stage of the case.

h. DTPA

Defendants argue that Plaintiff's claims under the Texas Deceptive Trade Practices Act ("DTPA") fail under the learned intermediary doctrine and for the same reasons that her fraud-based claims fail. As discussed above, the Court is persuaded that there are fact issues as to whether Plaintiff has overcome the learned intermediary doctrine and whether circumstances existed giving rise to a duty for Defendants to disclose additional information. Thus, Part VII of Defendants' Motion is **DENIED**.

i. Exemplary damages

Defendants argue that Plaintiff has no evidence that any act or omission by Zimmer acted with fraud, malice, or gross negligence, or that Zimmer had actual, subjective awareness of any risk to Plaintiff at the time the device was implanted. (Dkt. No. 178 at 29.) However, Plaintiff has presented evidence that could support an award of exemplary damages, including that at the time of plaintiff's implant surgery, Zimmer had no processes in place to validate the porosity of the devices being produced at its Puerto Rico plant. (*See* Dkt. No. 211-8.) In light of the evidence presented by Plaintiff, Part IV of Defendants' no evidence motion for summary judgment is **DENIED**.

II. Plaintiff's Motion for Summary Judgment

Plaintiff moves for summary judgment as to eighteen affirmative defenses raised by Defendants. The Court will address each affirmative defense in turn, grouping the defenses according to how Plaintiff found it appropriate to group such defenses.

a. First Affirmative Defense: Failure to State a Claim

Plaintiff argues that Defendants' first affirmative defense fails because it is moot in light of Plaintiff's Fourth Amended Complaint. As Plaintiff noted in its Motion, the deadline to file dispositive motions ran before Zimmer's deadline to file an Answer to Plaintiff's Fourth Amended Complaint. In fact, Plaintiff's entire Motion for Summary Judgment is based on an assumption that Defendants would file a nearly identical Answer to Plaintiff's Fourth Amended Complaint. (Dkt. No. 180 at 1 ("Mrs. Hardy anticipates that Zimmer will file the identical affirmative defenses in its Answer to the Fourth Amended Complaint, therefore Mrs. Hardy files this Motion for Partial Summary Judgment seeking judgment on certain affirmative defenses.")) As such, the Court rejects Plaintiff argument that this defense is moot.

In this defense, Defendants incorporate by reference the arguments made in their Motion for Summary Judgment (Dkt. No. 178). Given that this defense does not raise any issues beyond those raised in the summary judgment motion,¹ which will be disposed of by this Order, the Court is of the opinion that Part IV.A of Plaintiff's Motion should be **DENIED**. The applicability of this defense rises or falls with the Court's rulings on Defendants' summary judgment motion.

¹ The Court limits the extent of Defendants' first affirmative defense to the arguments incorporated by reference, due to Defendants' failure to provide any further specificity regarding the contents of its defense. *See Lebouef v. Island Operating Co.*, 342 F. App'x 983, 985 (5th Cir. 2009) (unpublished) ("[G]iven that there are nineteen affirmative defenses listed in rule 8(c), as well as other deficiencies that can cause failure to state a claim, the defendant must provide at least some information that alerts the plaintiff to what the alleged problem is. [Defendant's] unelaborated statement of failure to state a claim did not provide enough information to preserve its affirmative defense."). *See also E.E.O.C. v. Courtesy Bldg. Servs., Inc.*, No. 3:10-cv-1911-D, 2011 WL 208408, at *3 (N.D. Tex. Jan. 21, 2011) ("The defense of 'failure to state a claim' is so broad that it is unclear merely from an assertion of the name of the defense what the nature of the defense may be.").

b. Fifth Affirmative Defense: Compliance with Relevant Standards

Defendants' fifth affirmative defense states that Plaintiff cannot recover because Defendants complied with all applicable codes, standards, regulations, or specifications established, adopted, promulgated, or approved by the United States, the State of Texas, or by an agency of the United States or the State of Texas. (Dkt. No. 197 at 53.) Plaintiff argues that the FDA has notified Zimmer on several occasions that it has not complied with federal statutes and regulations. Although Part IV.B of Plaintiff's Motion does not identify specifically which evidence Plaintiff relies on to support this argument, the Court assumes Plaintiff was referring to the statement of facts regarding the FDA Form 483 letters and FDA Warning Letter that Zimmer received. (*See* Dkt. No. 180 at 2–4.) Although these documents appear to be some evidence of noncompliance, the Court is not persuaded that Plaintiff has met her burden on this point at the summary judgment stage. For example, it is unclear whether the Form 483 letters are merely “observations” or if they are reliable evidence of regulatory violations. As such, the Court finds it appropriate to **DENY** Part IV.B of Plaintiff's Motion and consider the evidence presented on this point at trial.

c. Sixth, Seventh, Ninth, and Seventeenth Affirmative Defenses: Learned Intermediary Doctrine, Assumption of Risk, Etc.

Plaintiff argues that these four affirmative defenses are related and should all be removed from this case based, essentially, on Zimmer's alleged failure to disclose important information about the Trilogy shells. (Dkt. No. 180 at 6–7.)

As discussed above, there are genuine issues of material fact regarding whether circumstances existed under which Defendants had a duty to disclose further information and

whether the lack of such additional information caused Plaintiff's injuries. As such, Part IV.C of Plaintiff's Motion is **DENIED**.

d. Eighth Affirmative Defense: State of the Art

Plaintiff argues that there is no evidence to support Zimmer's defense that the products at issue were in conformity with the generally recognized state of the art at the time the products were designed, manufactured, packaged, and labeled. (Dkt. No. 180 at 7–8.) Based on the briefing, the Court is not persuaded that a grant of summary judgment it is appropriate. As such, Part IV.D of Plaintiff's Motion is **DENIED**.

e. Thirteenth and Twenty-Fourth Affirmative Defenses: Preemption

Plaintiff argues that Defendants' affirmative defense based on federal preemption does not apply in this case. (Dkt. No. 180 at 8.) However, as noted previously, Plaintiff's Complaint appears to present more than one factual basis to support her various claims, including her fraud by nondisclosure claim. As such, the Court finds it appropriate to **DENY** Part IV.E of Plaintiff's Motion and to allow Defendants' preemption defense to remain in this case for now.

f. Fourteenth Affirmative Defense: Failure to Mitigate Damages

Plaintiff argues that there is no evidence that Mrs. Hardy failed to properly seek medical treatment when she knew or should have known such treatment was necessary. (Dkt. No. 180 at 9.) In response, Zimmers points to deposition testimony from Dr. Phillips, Mrs. Hardy's treating physician, indicating that he instructed her to return for a follow up appointment in six months, but that she never did so according to his knowledge. (*See* Dkt. No. 203-1 at 21.)

A reasonable fact-finder could consider this evidence and find a failure to exercise reasonable care in minimizing damages. Accordingly, Part IV.F of Plaintiff's motion for summary

judgment is **DENIED**, and Zimmer’s defense of failure to mitigate damages remains a live issue for trial.

g. Eighteenth and Twenty-Third Affirmative Defenses: Collateral Source Issues

Defendants’ eighteenth affirmative defense states that “To the extent Plaintiff is seeking recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Fourth Amended Complaint, such benefits are not recoverable in this action.” (Dkt. No. 197 at 56.) Likewise, Defendants’ twenty-third defense states that “Any verdict or judgment rendered against Defendants must be reduced by those amounts that have been, or will, with reasonable certainty, replace or indemnify Plaintiff, in whole or in part, for any past or future claimed economic loss, from any collateral source such as insurance, social security, workers’ compensation, or employee benefit programs.” (Dkt. No. 197 at 58.)

Plaintiff argues that Defendants’ two affirmative defenses related to reducing the amount of damages she may collect relate to an evidentiary rule (the collateral source doctrine) that prevents Defendants from introducing evidence of benefits, such as health insurance, that the Plaintiff may have received from outside sources. (Dkt. No. 180 at 9–10.) Defendants respond that under *Haygood v. De Escabedo*, 356 S.W.3d 390 (Tex. 2011), Defendants are entitled to offset Plaintiff’s damages, if any, by amounts that were paid for by third-parties, including insurance. (Dkt. No. 203 at 11.) However, Defendants misread the Texas Supreme Court’s opinion in *Haygood*.

Haygood involved a situation where a plaintiff had sought and a jury had awarded a damages amount for medical expenses that was based on the full bill that the plaintiff had received from the health care providers. *Haygood*, 356 S.W.3d at 392–93. This bill reflected the “list” price

that the health care providers would ideally charge, rather than the adjusted price agreed to between the health care provider and the insurance company. *Id.* The jury had awarded damages based on the full list price despite the fact that the health care providers had adjusted those bills based on their relationship with Medicare, which resulted in a cost almost \$80,000 lower than what the health care providers had listed on the bill. *Id.* On appeal, the Texas Supreme Court held that the common law collateral source rule does not allow recovery of medical damages that a health care provider is not entitled to charge. *Id.* The Court also held that Section 41.0105 of the Texas Civil Practice and Remedies Code limits a plaintiff's recovery of medical expenses to those "which have been or must be paid by or for the claimant." *Id.* at 398. Thus, the Court held that the plaintiff was not entitled to recover damages for the adjustments to the plaintiff's bill. In other words, the plaintiff could not recover medical expenses that neither the plaintiff nor the insurance company actually paid. However, the plaintiff could recover medical expenses actually paid by the insurance company.

Defendants' affirmative defenses reach further than the holding in *Haygood*. Accordingly, Part IV.G of Plaintiff's Motion is **GRANTED**.

h. Nineteenth Affirmative Defense: Safer Alternative Design

Plaintiff seeks to strike Defendants' affirmative defense that Plaintiff failed to assert a safer alternative design. (Dkt. No. 180 at 10.) As discussed above, Plaintiff has identified some evidence that could support an assertion of a safer alternative design. However, the evidence adduced at this point is insufficient to warrant striking Defendants' affirmative defense as to this issue. As such, Plaintiff has not met her summary judgment burden and Part IV.H of Plaintiff's Motion is **DENIED**.

i. Twentieth and Twenty-first Affirmative Defenses: DTPA

Plaintiff asks the Court to strike Defendants’ affirmative defenses related to the DTPA because, according to Plaintiff, Zimmer’s assertion that it did not engage in deceptive conduct is contradicted by its failure to disclose that the Trilogy shells lacked the required porosity and that Zimmer had no process to validate porosity. (Dkt. No. 180 at 10–11.) Plaintiff also baldly argues that she is a consumer who has certain economic damages. Even if these assertions are supported by the general evidence presented at the outset of Plaintiff’s Motion, the Court is not persuaded that such evidence is sufficient to satisfy Plaintiff’s summary judgment burden. As such, Part IV.I of Plaintiff’s motion is **DENIED**.

j. Twenty-Second Affirmative Defense: Punitive Damages

Defendants’ twenty-second affirmative defense argues that Plaintiffs’ claim for punitive damages violates, and it is therefore barred by, the Fourth, Fifth, Sixth, Eighth, and Fourteenth Amendments to the U.S. Constitution. (Dkt. No. 197 at 57–58.) The U.S. Supreme Court has held that punitive damages are not entirely barred by the Constitution, although such damages may violate due process if they are excessive. *BMW of North America, Inc. v. Gore*, 517 U.S. 559, 568 (1996) (citing *Gertz v. Robert Welch, Inc.*, 418 U.S. 323, 350 (1974)).

“Punitive damages may properly be imposed to further a State’s legitimate interests in punishing unlawful conduct and deterring its repetition.” *Id.* “States necessarily have considerable flexibility in determining the level of punitive damages that they will allow in different classes of cases and in any particular case.” *Id.* The Texas Civil Practice and Remedies Code § 41.003(b) establishes that a plaintiff may recover punitive damages if he or she can establish the requisite elements by clear and convincing evidence. Tex. Civ. Prac. and Rem. § 41.003(b). “The Texas

system in general provides sufficient restraints on the award of exemplary damages to satisfy due process and due course of law requirements.” *Missouri Pacific R. Co. v. Lemon*, 861 S.W. 2d 501, 525 (Tex. App.—Houston [14th Dist.] 1993).

Accordingly, the Court is persuaded that Part IV.J of Plaintiff’s Motion should be **GRANTED**. However, this ruling does not indicate that Plaintiff is in any way entitled to punitive damages, as Plaintiff must satisfy her high burden to prove that such damages are appropriate. Moreover, this ruling does not preclude Defendants from later challenging such damages, if awarded.

k. Twenty-Eighth Affirmative Defense: Estoppel, Unclean hands, Waiver, Regulatory compliance

Defendants’ twenty-eighth defense states that Plaintiff’s claims may be barred by the doctrines of estoppel, unclean hands, waiver, and regulatory compliance.

As to estoppel, unclean hands, and waiver, Plaintiff argues that Defendants have presented no evidence to support such defenses. (Dkt. No. 180 at 11–12.) Instead of responding to Plaintiff’s no evidence summary judgment motion by providing specific evidence, Defendants instead argue that Plaintiff has not provided any evidence to carry her burden.

“[A] party seeking summary judgment always bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of ‘the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any,’ which it believes demonstrate the absence of a genuine issue of material fact.” *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). “This initial burden remains with the moving party even when the issue involved is one on which the non-movant will bear the burden of proof at trial.” *Russ v. Int’l Paper Co.*, 943 F.2d 589, 592 (5th Cir. 1991). However, such burden “may be discharged by

‘showing’—that is, pointing out to the district court—that there is an absence of evidence to support the nonmoving party’s case.” *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986). Thus, the Fifth Circuit has held that when the party seeking summary judgment does not bear the burden of proof at trial on the issue, that party is “not required to ‘produce evidence negating the existence of a material fact’”, but rather bears the burden “only [to] point out the absence of evidence supporting the nonmoving party’s case.” *Skotak v. Tenneco Resins, Inc.*, 953 F.2d 909, 913 (5th Cir. 1992), opinion corrected (Mar. 26, 1992) (quoting *Latimer v. Smithkline & French Laboratories*, 919 F.2d 301, 303 (5th Cir.1990)).

As such, after Plaintiff pointed out the lack of evidence to support these three theories, it became Defendants’ burden to submit evidence in support of these defenses. Although Defendants indicate that these defenses “relate” to the failure to mitigate damages defense, Defendants have not explained how the evidence used to support that defense could be used to support the separate defenses of estoppel, unclean hands, and waiver. As such, Part IV.K of Plaintiff’s Motion is **GRANTED** with respect to estoppel, unclean hands, and waiver.


As to regulatory compliance, Plaintiff repeats her argument used in her Motion with regard to Defendants’ fifth affirmative defense (compliance with relevant standards). Consistent with the Court’s ruling as to that aspect of Plaintiff’s Motion, and for the same reasons, Plaintiff’s Motion is **DENIED** with respect to regulatory compliance.

I. Twenty-ninth Affirmative Defense

In light of Zimmer’s Answer to Plaintiff’s Fourth Amended Complaint (Dkt. No. 197), in which Zimmer no longer asserts that Plaintiff’s claims may be barred by the doctrines of res

judicata, collateral estoppel, issue preclusion, and/or claim preclusion, Part IV.L of Plaintiff's Motion is **DENIED AS MOOT**.

So ORDERED and SIGNED this 28th day of April, 2017.



RODNEY GILSTRAP
UNITED STATES DISTRICT JUDGE